DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 23, 2016

Quality in Flow, Ltd.
% John Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, DC 20004

Re: K150404
Trade/Device Name: QiF Blood and Fluid Warmer
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LGZ, BSB
Dated: April 22, 2016
Received: April 22, 2016

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang
-S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K150404

Device Name

QiF Blood and Fluid Warmer

Indications for Use *(Describe)*

The QiF Blood and Fluid Warmer device is intended for warming blood, blood products, and intravenous fluids prior to administration. It is intended to be used by healthcare professionals in hospital, clinics and field environments, to help prevent hypothermia.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Quality in Flow Ltd. QiF Blood and Fluid Warmer

K150404

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Name:	Quality in Flow Ltd.
Address:	Kibutz Einat POB 29 Israel 4880500
Phone:	+972-54-6600-146
Contact Person:	Neta Sherman Director Product Realization
Additional Contact Person:	Tsvia Erlich Senior Regulatory Affairs Consultant

Date Prepared: June 21, 2016

Name of Device and Name/Address of Sponsor

Trade Name: QiF Blood and Fluid Warmer

Sponsor Address: Quality in Flow Ltd.
Kibutz Einat
POB 29
Israel 4880500

Common or Usual Name

Sterile Fluid Path, in-line Blood Fluid Warmer

Classification Code and Name

LGZ - Warmer, Thermal, Infusion Fluid, Class 2 (21 C.F.R 880.5725)
BSB - Warmer, Blood, Non-electromagnetic radiation, Class 2

Predicate Devices

VITAL SIGNS, Inc. (a GE Healthcare Company), enFlow IV Fluid Warmer (K112902)

Intended Use / Indications for Use

The QiF Blood and Fluid Warmer device is intended for warming blood, blood products, and intravenous fluids prior to administration. It is intended to be used by healthcare professionals in hospital, clinics and field environments, to help prevent hypothermia.

Technological Characteristics

The Quality in Flow Ltd. QiF Blood and Fluid Warmer device is a portable, sterile Fluid Path, in-line Blood and Fluid Warmer. The device is comprised of a Base Unit and a sterile disposable cartridge (Disposable Unit). The device is located between the fluid container (intravenous fluid, blood or blood product) and treated patient, outside of the patient's body. The Disposable Unit is composed of a plastic oval box encasing a spiral stainless steel heat exchanger tube. The Base Unit contains Firmware (software) and electronics (HW). The base Unit controls the performance of the system and the fluid outflow temperature. The power source is a rechargeable detachable battery located within the Base Unit. The disposable unit cartridge (blood/fluid) is provided with inlet and outlet luers that connect to standard IV tubing.

Performance Data

Quality In Flow Ltd. performed the following testing and Design Control activities, as described within the 510(k) submission, to evaluate the QiF Blood and Fluid Warmer device and demonstrate substantial equivalence to the identified predicate:

- Software Verification and Validation was performed in compliance with "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", issued on May 11, 2005 (the Software Guidance)", and EN IEC 62304:2006/AC:2008. Software level of concern is moderate.

- Bench testing to evaluate the performance and functionality of the device including:

    - Hemolysis study evaluated by flowing and warming blood products under normal and worse-case conditions (such as stop flow, high flow rate and air bubble), in compliance with ASTM 2172:[(2002) Reapproved 2011)] and in addition flowing and heating old RBC blood product in high and low flow rates. No protocol deviations that affected the results took place. All samples met the acceptance criteria which is hemolysis of up to 1%.
    - Bench testing to demonstrate temperature indication accuracy, outflow temperature profile under normal and abnormal (such as stop flow, high flow rate and air bubble) flow scenarios, fluid path integrity under pressure in compliance with ASTM 2172: [(2002) Reapproved 2011)], and battery capacity in terms of minimal heated volume. No protocol deviations that affected the results took place. All the tests met the acceptance criteria which were determined according to the product design input requirement specifications.

- Biocompatibility testing (ISO 10993-5:2009, 10993-10:2010, 10993-11:2006, ASTM F756:2008)

- Leachability testing was performed on fluid that was flown and heated by the QiF device, the analysis of the fluid was done by external certified lab. There were no protocol deviations. Pass criteria - no significant change in the concentration of new materials not present in the fluid prior to heating

and no significant change in the concentration of any of the detected materials between results obtained with control sample and test article. All test samples met the acceptance criteria.

- Sterilization and Shelf Life validation were conducted in compliance with ISO 11135-1:2007, ISO 11737-1:2006, ISO 10993-7:2008, and FDA CDRH, Shelf Life of Medical Devices guidance, April 1991.

- Electrical Safety and EMC testing (IEC 60601-1:2012, 60601-1-2:2007 ed. 3.0, 60601-1-6:2010, 60601-1-11:2010).

- Battery testing per IEC 62133:2012.

In all instances, the QiF Blood and Fluid Warmer device performed as intended and met the acceptance criteria as set by the company or by the applicable standards.

Substantial Equivalence

The QiF Blood and Fluid Warmer device is substantially equivalent to the cleared Enginivity LLC enFlow IV Fluid Warmer. The QiF Blood and Fluid Warmer has the same intended uses and indications. The technological characteristics and principles of operation are substantially similar, both the QiF Blood and Fluid Warmer and the enFlow IV Fluid Warmers are composed of a warming reusable unit and a sterile, disposable, single patient use cartridge. The reusable warming unit of the subject and predicate devices controls the operation of the system and the outflow temperature of the infusate and contains software, hardware and the power source. The subject and predicate device use the same heating method, i.e., resistive heating. The disposable cartridge of both the subject and predicate devices contains a fluid path that serves as a heat exchanger. The heat exchanger of the subject and predicate devices contains metal that heat the blood, blood product or intravenous fluid by resistive heating method. The only main technological differences between the QIF device and its predicate are: the material composition of the heat exchanger fluid path, maximum output temperature, and presence of electrical and thermal insulation by shielding the QIF device Disposable Unit. These differences do not raise any new questions of safety and effectiveness and equivalent performance has been demonstrated by the hemolysis tests. Thus, the QiF Blood and Fluid Warmer is substantially equivalent. Detailed comparison between the predicate and the subject device is provided in the table below:

Substantial Equivalence Chart:

	QiF Blood and Fluid Warmer (Subject Device)	***enFlow IV Fluid Warmer*** (K112902)
Indication for Use	Intended for warming blood, blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments to help prevent hypothermia.	Intended for warming blood, blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments to help prevent hypothermia.
Intended Use	Medical emergencies or surgeries where warm fluid administration is required to treat the patient. Whenever parenteral introduction of normothermic fluid are desired or indicated	Medical emergencies or surgeries where warm fluid administration is required to treat the patient. Whenever parenteral introduction of normothermic fluid are desired or indicated
User Population	Healthcare professional (i.e. paramedic, nurse doctor etc.)	Healthcare professional (i.e. paramedic, nurse doctor etc.)
User Interface / Notifications	Visual (LCD display) and audio	Visual (LED) and audio
Notification Types	Overheat Under heat Low battery Stop Flow	Overheat Under heat Low battery
Usage environment	Clinic and Field	Clinic and Field
System components	Warmer with display and a sterile disposable heat exchanger	Warmer with display and a sterile disposable heat exchanger
Infusion temp.	38±2°C	Up to 40°C (± 2 °C)
Heating Method	Resistive heating	Resistive heating
Fluid Path	Located within the sterile disposable cartridges (DU). Spiral stainless steel tube and a short segment of a PVC tube	The sterile disposable cartridges consist of a plastic housing and biocompatible coated aluminum extrusion which when combined

	The tube serves as the conductor of electrical current.	form an enclosed fluid path.
Flow Rate	Based on Gravity, ~ 160 ml/min	Based on Gravity, Up to 200 ml/min
Warmer Type	Inline warmer	Inline warmer
Power Source	Rechargeable battery	Rechargeable battery 110-120 or 220-240 VAC
Biocompatibility	The fluid path is made of biocompatible Stainless Steel and PVC	The fluid path is made of biocompatible coated aluminum extrusion
Software	The software control the heating process and the operation of the device	The software control the heating process and the operation of the device
Sterilization	The disposable unit is provided sterile for single patient use	The disposable unit is provided sterile for single patient use
Product specific Standard with which the Device Complies	ASTM 2172:2002,Standard specification for blood/Intravenous Fluid Irrigation Fluid Warmers	ASTM 2172:2002,Standard specification for blood/Intravenous Fluid Irrigation Fluid Warmers

Conclusions

Based on comparison to the predicate device and completed performance testing, including biocompatibility, hemolysis, and leachability testing, as well as bench testing intended to demonstrate that the device meets it specifications and performs as intended, the QiF Blood and Fluid Warmer is substantially equivalent to the predicate device.